

Application No. 09/626,636  
Amendment dated October 31, 2007

### REMARKS

Applicant amended claims 172, 207, 208, 212, 219, 248, 305 and 338, and added new claims 344-350 to further define Applicant's invention. Support for new claims 344-350, can be found in Applicant's specification at least at page 49, line 34 through page 50, line 1 and in Figs. 5, 6, 7D and 7F.

In the Office Action of July 23, 2007, the Examiner rejected claims 172, 219, 248, and 338 (including independent claims 172 and 248) under 35 U.S.C. § 112, second paragraph. According to the Examiner, "it is unclear what surface is concave and oriented toward and approximating the contour of the vertebral bodies." In response, Applicant has amended independent claims 172 and 248, and amended dependent claims 219 and 338 with additional recitations regarding the structure of the distal end of the guard. Applicant submits that support for independent claims 172 and 248, and dependent claims 219 and 338 is found at least in Applicant's specification at page 49, line 34 through page 50, line 1 and in Figs. 7D and 7F. As such, Applicant submits that the Examiner's rejection under 35 U.S.C. § 112, second paragraph, has been overcome.

The Examiner rejected claims 172-176, 178-184, 190-195, 201, 202, 207-226, 237, 238, 247-256, 258-276, and 278-343 (including independent claims 172, 207, 248, 289, and 332) under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 5,015,255 to Kuslich ("Kuslich '255") in view of U.S. Patent No. 5,049,150 to Cozad ("Cozad"). As discussed below, neither Kuslich '255, Cozad, nor a proper combination thereof teach or suggest Applicant's invention as claimed in independent claims 172, 207, 248, 289, and 332.

Recently, in KSR International Co. v. Teleflex Inc. et al., the Supreme Court reaffirmed the framework for governing obviousness under 35 U.S.C. § 103(a) is set forth in Graham et al. v. John Deere Co. of Kansas City et al., 383 U.S. 1, 148 U.S.P.Q. 459 (1966). (See KSR v. Teleflex, 127 S.Ct. 1727 (2007)). Under Graham v. John Deere, the question of obviousness is resolved on the basis of factual determinations

Application No. 09/626,636  
Amendment dated October 31, 2007

including (1) the scope and content of the prior art, (2) the differences between the claimed invention and the prior art, (3) the level of ordinary skill in the pertinent art, and (4) where in evidence, so-called secondary considerations. (Graham v. John Deere, at 17-18, 148 U.S.P.Q. at 467). However, even under Graham v. John Deere, a combination of references that does not teach or suggest every element of the claimed invention, or references that teach away from the claimed invention support a finding of nonobviousness. As discussed below, the Examiner's asserted combination of Kuslich '255 and Cozad does not teach or suggest all of the limitations of independent claims 172, 207, 248, 289, and 332, and, therefore, Applicant submits that a prima facie case of obviousness has not been made.

Note that Kuslich '255 discloses a tool (22) with a shaft (24) having a distal end (26), and cutting blades (40) and (42) deployable through a slot (35) formed in the shaft (24). The tool (22) deploys the cutting blades (40) and (42) to ream "an enlarged cavity on the interior of the opposing vertebra (sic) bodies and removes the degenerative disc material." (Kuslich '255, column 3, lines 3-5). As shown in Fig. 19, the shaft (24) including the distal end (26) thereof is sized to be partially received within a bore (100) previously formed between vertebral bodies (10a) and (10a'). The cutting blades (40) and (42) are then deployed, and the tool (22) is rotated to form an enlarged chamber (102).

Kuslich '255 discloses that the tool (22) can be inserted into the bore (100) in an unguided or a guided manner. When guided into the bore (100), a locating cylinder (104) (that does not include any openings through the sides thereof) is utilized to position the tool (22). When using the locating cylinder (104), a contact surface at an end of the locating cylinder (104) is contacted to the vertebral bodies (10a) and (10a'), and, thereafter, the tool (22) is guided through the locating cylinder (104) into the bore (100). Therefore, the tool (22) and the locating cylinder (104) are separate and distinct components. Furthermore, the contact surface of the end of the locating cylinder (104) appears to be flattened in a plane perpendicular to the longitudinal axis thereof. As

Application No. 09/626,636  
Amendment dated October 31, 2007

such, the contact surface of the end of the locating cylinder (104) does not have a concave curvature that could be oriented toward the adjacent vertebral bodies, and the locating cylinder (104) does not include any openings through the sides thereof.

Note also that Cozad discloses a tool (10) having a first member (12) and a second member (14). The first member (12) can be received through the second member (14). The second member (14) includes a plurality of teeth (36) extending from a leading end (34) thereof. However, the plurality of teeth (36) appear to terminate at a plane perpendicular to the longitudinal axis of the second member (14). Furthermore, the second member (14), like the locating cylinder (104) of Kuslich '255, does not include any openings through the sides thereof.

In rejecting independent claims 172, 207, 248, 289, and 332 based on the combination of Kuslich '255 and Cozad in the Office Action dated July 23, 2007, the Examiner indicates that Kuslich '255 discloses "guard (24)" and "openings (35, fig. 11)" and Cozad discloses "guard for bone surgery and including engaging portions and flat portions as claimed (fig. 1) for preventing over-penetration of the engaging portions into bone." According to the Examiner, "it would have been obvious to one having ordinary skill in the art at the time the invention was made to employ the engaging portion and flat portions in view of Cozad into Kuslich's guard sleeve (104) in order to provide an engage (sic) mechanism that prevent (sic) the guard from moving so that the insertion could be more accurate."

However, regarding amended independent claims 172 and 248, and amended dependent claims 224, 305, and 338 based on the combination of Kuslich '255 and Cozad, Applicant submits that neither Kuslich '255, Cozad, nor a proper combination thereof teach or suggest a hollow tubular guard or hollow guard with the distal end of the guard having a concave curvature being at least in part curved in a plane parallel to the mid-longitudinal axis and oriented toward and approximating the contour of the face of the adjacent vertebral bodies (amended independent claims 172 and 248, and amended dependent claims 219 and 338), or a guard having a distal end being at least in part curved in a plane parallel to the central longitudinal axis and oriented toward and

Application No. 09/626,636  
Amendment dated October 31, 2007

contoured to the curvature of the adjacent vertebral bodies to permit an intimate fit between said guard and the adjacent vertebral bodies (amended dependent claim 305). Accordingly, because the combination of Kuslich '255 and Cozad does not teach or suggest all the claim limitations, the Examiner has not made a showing of a prima facie case of obviousness, and the rejection of independent claims 172 and 248, and dependent claims 224, 305, and 338 based thereon is deemed to be overcome.

In the Office Action of July 23, 2007, regarding the rejection of independent claims 207, 289, and 332 based on the combination of Kuslich '255 and Cozad, Applicant reiterates that the Examiner has conflated what the Examiner calls "guard (24)" and "Kuslich's guide sleeve (104)" together. What the Examiner calls "guard (24)" and "Kuslich's guard sleeve (104)" are actually separate and distinct from one another. The "guard (24)" is in actuality the shaft (24) of the tool (22), and the "guide sleeve (104)" is in actuality the locating cylinder (104), that are separate and distinct components.

In response to Applicant's arguments, the Examiner indicates "that both the sleeve 104 and shaft 24 of Kuslich '255 can be interpreted as guards" in the Advisory Action dated October 18, 2007. However, because what the Examiner now calls the "sleeve 104" (previously called "Kuslich's guard sleeve (104)") is configured to receive what the Examiner now calls the "shaft 24" (previously called "guard (24)") therethrough, but not vice versa, the Examiner's assertion contradicts the teachings of Kuslich '255. Moreover, the cutting blades (40) and (42) are provided on the interior of the shaft (24), and the locating cylinder (104) does not include a slot similar to the slot (35) formed in the shaft (24). Therefore, without further modifications, which the Examiner indicates in the Advisory Action dated October 18, 2007 have not been suggested, neither the shaft (24) of the tool (22) nor the locating cylinder (104) teaches or suggests a hollow tubular guard or a hollow guard as recited in independent claims 207, 289, and 332.

As such, Applicant submits that neither Kuslich '255, Cozad, nor a proper combination thereof teach or suggest a hollow tubular guard or a hollow guard having a

Application No. 09/626,838  
Amendment dated October 31, 2007

passage for providing guided access to a disc space, and having a proximal end and an opposite distal end and sides therebetween with "openings in said sides" (independent claim 207) or "openings through said sides" (independent claim 289), or a hollow guard having a passage for providing guided access to a disc space, and having a proximal end, an opposite distal end, and a wall that is continuous around the mid-longitudinal axis of the guard, the guard having "an opening through said wall" (independent claim 332). Accordingly, because the combination of Kuslich '255 and Cozad does not teach or suggest all the claim limitations, the Examiner has not made a showing of a prima facie case of obviousness, and the rejection of independent claims of 207, 289, and 332 based thereon is deemed to be overcome.

Also, note that the Examiner's rejection under 35 U.S.C. § 103(a) based on Kuslich '255 in view of Cozad in further view of U.S. Patent No. 5,489,307 to Kuslich is moot because of the above-discussed allowable subject matter of independent claims 172, 207, 248, 289, and 332.

Claims 172-184, 201, 202, 247-269, 276, 278-288 and 331-343 (including independent claims 172, 248, and 332) were rejected under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 3,848,601 to Ma ("Ma") in view of known art. In rejecting claims 172-184, 201, 202, 247-269, 276, 278-288 and 331-343, the Examiner also cites U.S. Patent No. 5,058,275 to Staubli ("Staubli"). Staubli is provided to support the Examiner's contention that "it is known in the art to have a depth limit configuration including a flat portion between the engaging portions of penetrating portions." However, the only "flat portion" discussed in Staubli is labeled with the numeral (44). The flat portion (44) serves as a keyway for receiving a spring-loaded latch (47) in order to maintain a shaft in position relative to a tool holder. As such, Applicant reiterates that Staubli does not support the Examiner's contention that "it is known in the art to have a depth limit configuration including a flat portion between the engaging portions of penetrating portions."

Note that Ma discloses a chisel (50) positioned along the spine that is configured to receive a section of disc (24) and portions (20a) and (22a) of vertebrae (20) and (22),

Application No. 09/626,636  
Amendment dated October 31, 2007

respectively. A drill bit (62) is inserted through the chisel (50) to remove the section of the disc (24) and portions (20a) and (22a), and form one of cavities (74) and (75). However, before implantation of a bone plug (32), the chisel (50) is removed from the spine, and a bone plug injector (80) is received in one of the cavities (74) and (75).

The bone plug injector (80) of Ma includes an end (89), and relies on contact of the end (89) with the end portions of the cavities (74) and (75) to limit the insertion thereof. The end (89) includes a contact surface for contacting the end portions of the cavities (74) and (75). However, the contact surface of the end (89) appears to be flattened in a plane perpendicular to the longitudinal axis of the bone plug injector (80). As such, the contact surface of the end (89) does not have a concave curvature that could be oriented toward adjacent vertebral bodies, and does not include extensions with flat portions therebetween.

Accordingly, Ma does not teach or suggest a hollow tubular guard or hollow guard with "said distal end of said guard having a concave curvature being at least in part curved in a plane parallel to the mid-longitudinal axis and oriented toward and approximating the contour of the face of the adjacent vertebral bodies," as recited in independent claims 172 and 248. Furthermore, Ma does not teach or suggest a hollow guard "having extensions at said distal end of said guard, at least of two of said extensions being adapted to penetrate the disc space between the adjacent endplates of the adjacent vertebral body," and "having a flat portion between at least some of said extensions for preventing over-penetration said extensions into the spine", as recited in independent claims 248 and 332. Therefore, because Ma does not teach or suggest all the claim limitations, the Examiner's rejection of independent claims 172, 248, and 332 based thereon under 35 U.S.C. § 103(a) is deemed to be overcome.

Moreover, in the Advisory Action of October 18, 2007, the Examiner indicates that Cozad "is another example showing its well known to have the flat portions

Application No. 09/626,636  
Amendment dated October 31, 2007

between engaging portions. However, Applicant notes that Cozad does not teach or suggest a hollow tubular guard or hollow guard with "said distal end of said guard having a concave curvature being at least in part curved in a plane parallel to the mid-longitudinal axis and oriented toward and approximating the contour of the face of the adjacent vertebral bodies," as recited in independent claims 172 and 248. Furthermore, Applicant notes that Cozad does not teach or suggest hollow guard having a passage for providing guided access to a disc space, and having a proximal end, an opposite distal end, and a wall that is continuous around the mid-longitudinal axis of the guard, the guard having "an opening through said wall," as recited in independent claim 332.

Also, claims 172-184, 201, 202, 247-269, 276, 278-288 and 331-343 (including independent claims 172, 248, and 332) were rejected under 35 U.S.C. § 103(a) as being unpatentable over Codman Signature Series 4 ("Codman") in view of Cozad. Note that Codman discloses a drill guide depicted in Figs. 21-23 and 25. The drill guide is positioned relative to the spine and vertebral bodies, and a drill bit is received therethrough to drill a hole in the spine. In doing so, a contact surface of the drill guide is contacted to the vertebral bodies, and the drill bit received in the drill guide. (See Codman, Figs. 21-23 and 25). Thereafter, the drill guide is removed prior to insertion of a dowel or bone graft. (See Codman, Figs. 21, and 35-37). As shown in Fig. 21, the contact surface of the drill guide appears to be flattened. As such, the contact surface of the drill guide does not have a concave curvature that could be oriented toward the adjacent vertebral bodies, and Codman does not teach that the drill guide is configured to receive a spinal implant therethrough.

In rejecting independent claims 172, 248, and 332 in the Office Action of July 23, 2007, the Examiner indicates that "although the drill guide may be removed prior to insertion of a graft or dowel, the guide is capable of being left in place to assist implantation of a graft or dowel." According to the Examiner, "the limitations 'having a passage for providing guided access to a disc space and vertebral bodies adjacent the

Application No. 09/626,636  
Amendment dated October 31, 2007

disc space' and 'the permit the movement of a spinal implant therethrough' [are] merely functional limitations, and thereby [a] structure *capable* of performing the recited functional limitation meets the claim limitations." Furthermore, in the Advisory Action of October 18, 2007, the Examiner indicates the following:

Regarding applicant's assertion regarding the rejection using Codman in view of Cozad, Examiner notes that the capability is described in the primary reference (sic) (Codman) and that the teachings of Cozad are employed for an entirely different reason than the functional limitations that applicant argues. To clarify, even without the engaging portions of Cozad, the device of Codman is capable of having the guide left in place to assist in implantation. The teaching of Cozad to modify the Codman device does not change this capability and as such, the entire structure of the claim is present in that rejection, and therefore applicant's arguments are not persuasive.

However, Applicant submits that inquiries regarding the "capability" of a reference's structure are only relevant for anticipation under 35 U.S.C. § 102, and are not relevant for a determination of obviousness under 35 U.S.C. § 103(a). Instead, the focus under 35 U.S.C. § 103(a) is on the teachings of a reference. According to MPEP § 2114, quoting Ex parte Masham, 2 USPQ.2d 1647 (Bd. Pat. App. & Inter. 1987), "a claim containing a 'recitation with respect to the manner in which a claimed apparatus is intended to be employed does not differentiate the claimed apparatus for a prior art apparatus' if the prior apparatus teaches all the structural limitations of the claim." Accordingly, the converse is also true. Therefore, a recitation with respect to the manner in which a claimed apparatus is intended to be employed can differentiate the claimed apparatus from a prior art apparatus if the prior art apparatus does not teach all the structural limitations of the claim.

Because Cozad is employed in combination with Codman under 35 U.S.C. § 103(a), the Examiner impliedly admits that Codman does not teach all of the limitations of the rejected claims. Therefore, the teachings, not the capability, of Codman are only relevant under 35 U.S.C. § 103(a).

Accordingly, Applicant submits that Codman teaches away from the present invention as claimed in independent claims 248 and 332 because the drill guide is



Application No. 09/626,636  
Amendment dated October 31, 2007

removed prior to insertion of a dowel or bone graft. Therefore, because Codman does not teach that the drill guide is configured to receive a spinal implant therethrough, and, in fact, teaches away from receiving a spinal implant therethrough, neither Codman, Cozad, nor a combination thereof teach or suggest a hollow guard "having a passage for providing guided access to a disc space and vertebral bodies adjacent the disc space," where the passage is sized "to permit the movement of a spinal implant therethrough", as recited in independent claims 248 and 332. Furthermore, because the drill guide of Codman includes the flattened contact surface, and, as discussed above, the plurality of teeth (36) of Cozad appear to terminate at a plane perpendicular to the longitudinal axis of the second member (14), neither Codman, Cozad, nor a proper combination thereof teach or suggest a hollow tubular guard or hollow guard with "said distal end of said guard having a concave curvature being at least in part curved in a plane parallel to the mid-longitudinal axis and oriented toward and approximating the contour of the face of the adjacent vertebral bodies," as recited in independent claims 172 and 248. Therefore, because Codman, Cozad, or a combination thereof do not teach or suggest all the claim limitations, the Examiner's rejection of independent claims 172, 248, and 332 based thereon under 35 U.S.C. § 103(a) is deemed to be overcome.

Accordingly, Applicant submits that independent claims 172, 207, 248, 289, 332, and 350 are patentable and that dependent claims 173-175, 178-206, 208-247, 249-256, 258-276, 278-288, 290-331, 333-343, and 344-349 dependent from independent claims 172, 207, 248, 289, 332, or 350, or claims dependent therefrom, are patentable at least due to their dependency from an allowable independent claim.

In view of the foregoing remarks, it is respectfully submitted that the claims are patentable. Therefore, it is requested that the Examiner reconsider the outstanding rejections in view of the preceding comments. Issuance of a timely Notice of Allowance of the claims is earnestly solicited.

To the extent any extension of time under 37 C.F.R. § 1.136 is required to obtain entry of this reply, such extension is hereby respectfully requested. If there are any

Application No. 09/626,636  
Amendment dated October 31, 2007

fees due under 37 C.F.R. §§ 1.16 or 1.17 which are not enclosed herewith, including any fees required for an extension of time under 37 C.F.R. § 1.136, please charge such fees to our Deposit Account No. 50-3726.

Respectfully submitted,  
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